

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

Bret BERNER et al.

Serial No.: Divisional of 10/024,932

Group Art Unit: Unassigned

Filing Date: Filed Herewith

Examiner: Unassigned

Title: GASTRIC RETENTIVE ORAL DOSAGE FORM WITH RESTRICTED DRUG RELEASE IN THE LOWER GASTROINTESTINAL TRACT

INFORMATION DISCLOSURE STATEMENT

Mail Stop Patent Application
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is an Information Disclosure Statement submitted for the Examiner's consideration. Applicants respectfully request that the Examiner review and make of record the references identified below.

The references identified below were disclosed and/or cited in parent application Serial No. 10/024,932, filed December 18, 2001, and, as such, copies thereof are not included pursuant to the provisions of 37 CFR § 1.98(d).

PTO-1449 forms listing the references accompany this paper. Applicants would appreciate the Examiner's initialing and returning the forms to indicate that the references have been reviewed and made of record. The references are as follows:

U.S. PATENT DOCUMENTS		
Document No.	Issue Date / Publication Date	Patentee / Applicant
4,434,153	2/28/84	Urquhart et al.
4,690,824	9/1/87	Powell et al.
4,695,467	9/22/87	Uemura et al.
4,748,023	5/31/88	Tamás et al.
4,786,503	11/22/88	Edgren et al.
4,839,177	6/13/89	Colombo et al.
4,851,232	7/25/89	Urquhart et al.
4,865,849	9/12/89	Conte et al.

U.S. PATENT DOCUMENTS		
Document No.	Issue Date / Publication Date	Patentee / Applicant
4,910,021	3/20/90	Davis et al.
5,002,772	3/26/91	Curatolo et al.
5,007,790	4/16/91	Shell
5,064,656	11/12/91	Gergely et al.
5,085,865	2/4/92	Nayak
5,213,808	5/25/93	Bar-Shalom et al.
5,232,704	8/3/93	Franz et al.
5,393,765	2/28/95	infeld et al.
5,422,123	6/6/95	Conte et al.
5,425,950	6/20/95	Dandiker et al.
5,458,887	10/17/95	Chen et al.
5,458,888	10/17/95	Chen
5,464,633	11/7/95	Conte et al.
5,472,708	12/5/95	Chen
5,487,901	1/30/96	Conte et al.
5,508,040	4/16/96	Chen
5,549,913	8/27/96	Colombo et al.
5,582,837	10/10/96	Shell
5,609,590	3/11/97	Herbig et al.
5,626,874	5/6/97	Conte et al.
5,650,169	7/22/97	Conte et al.
5,651,985	7/29/97	Penners et al.
5,681,583	10/28/97	Conte et al.
5,688,776	11/18/97	Bauer et al.
5,736,159	4/7/98	Chen et al.
5,738,874	4/14/98	Conte et al.
5,780,057	7/14/98	Conte et al.
5,783,212	7/21/98	Fassihi et al.
5,811,126	9/22/98	Krishnamurthy
5,837,379	11/17/98	Chen et al.
5,840,329	11/24/98	Bai
5,840,332	11/24/98	Lerner et al.
5,861,173	1/19/99	Nishioka et al.
5,891,474	4/6/99	Busetti et al.
5,897,874	4/27/99	Stevens et al.
5,916,595	6/29/99	Chen et al.
5,945,125	8/31/99	Kim
5,972,389	10/26/99	Shell et al.
6,033,685	3/7/00	Qiu et al.
6,207,197	3/27/01	Illum et al.
6,261,601	7/17/01	Talwar et al.
6,340,475	01/22/02	Shell et al.
6,368,628	4/9/02	Seth
6,451,808	9/17/02	Cowles

U.S. PATENT DOCUMENTS		
Document No.	Issue Date / Publication Date	Patentee / Applicant
6,488,962	12/3/02	Berner et al.
2001/0018070	8/30/01	Shell et al.
Serial No. 09/425,491	Filed 10/22/99	Shell et al
Serial No. 10/029,134	Filed 10/25/01	Gusler et al.
Serial No. 10/045,823	Filed 11/6/01	Shell et al.
Serial No. 10/066,146	Filed 2/1/02	Lim et al.
Serial No. 10/152,914	Filed 5/20/02	Fara et al.

FOREIGN PATENT DOCUMENTS		
Document No.	Publication Date	Country
GB 1330829	9/19/73	United Kingdom
EP 0598309 B1	1/28/98	Europe
EP 0795324 A2	9/17/97	Europe
WO 96/32097 A1	10/17/96	PCT
WO 98/55107 A1	12/10/98	PCT
WO 00/23045 A1	4/27/00	PCT
WO 00/38650 A1	7/6/00	PCT
WO 01/32217 A3	5/10/01	PCT
WO 01/56544 A3	8/9/01	PCT
WO 01/97783 A1	12/27/01	PCT
WO 02/083687 A1	10/24/02	PCT

OTHER DOCUMENTS
ABRAHAMSSON et al. (1993), "Absorption, Gastrointestinal Transit, and Tablet Erosion of Felodipine Extended-Release (ER) Tablets," <i>Pharmaceutical Research</i> 10(5):709-714.
APICELLA et al. (1993), "Poly(ethylene oxide) (PEO) and Different Molecular Weight PEO Blends Monolithic Devices for Drug Release," <i>Biomaterials</i> 14(2):83-90.
COLUMBO et al. (1990), "Drug Release Modulation by Physical Restrictions of Matrix Swelling," <i>International Journal of Pharmaceutics</i> 63:43-48.
CONTE et al. (1996), "Modulation of the Dissolution Profiles from Geomatrix® Multi-Layer Matrix Tablets Containing Drugs of Different Solubility," <i>Biomaterials</i> 17(9):889-896.
DAVIS et al. (1986), "The Effect of Density on the Gastric Emptying of Single- and Multiple-Unit Dosage Forms," <i>Pharmaceutical Research</i> 3(4):208-213.
DESHPANDE et al. (1997), "Development of a Novel Controlled-Release System for Gastric Retention," <i>Pharmaceutical Research</i> 14(6):815-819.
GUSLER et al. (June 2001), "Pharmacokinetics of Metformin Gastric-Retentive Tablets in Healthy Volunteers," <i>The Journal of Clinical Pharmacology</i> 41(6):655-661.
HUBER et al. (1966), "Utilization of Hydrophilic Gums for the Control of Drug Release from Tablet Formulations. I. Disintegration and Dissolution Behavior," <i>Journal of Pharmaceutical Sciences</i> 55(9):974-976.
HWANG et al. (1998), "Gastric Retentive Drug-Delivery Systems," <i>Critical Reviews in Therapeutic Drug Carrier Systems</i> 15(3):243-284.
KATORI et al. (1995), "Estimation of Agitation Intensity in the GI Tract in Humans and Dogs Based on <i>in Vitro/in Vivo</i> Correlation," <i>Pharmaceutical Research</i> 12(2):237-243.

OTHER DOCUMENTS
KIM (1995), "Drug Release from Compressed Hydrophilic POLYOX-WSR Tablets," <i>Journal of Pharmaceutical Sciences</i> <u>84</u> (3):303-306.
KORSMEYER et al. (1983), "Mechanisms of Solute Release from Porous Hydrophilic Polymers," <i>International Journal of Pharmaceutics</i> <u>15</u> :25-35.
LAPIDUS et al. (1966), "Some Factors Affecting the Release of a Water-Soluble Drug from a Compressed Hydrophilic Matrix," <i>Journal of Pharmaceutical Sciences</i> <u>55</u> (8):840-843.
MAGGI et al. (2000), "Highly Swellable, Multi-Layer Tablets to Prolong the Residence Time of the Delivery Device in the Stomach," <i>Abstracts / Journal of Controlled Release</i> <u>64</u> :333-334.
MAGGI et al. (2000), "High Molecular Weight Polyethylene Oxides (PEOs) as an Alternative to HPMC in Controlled Release Dosage Forms," <i>International Journal of Pharmaceutics</i> <u>195</u> :229-238.
RAO et al. (1988), "Swelling Controlled-Release Systems: Recent Developments and Applications," <i>International Journal of Pharmaceutics</i> <u>48</u> :1-13.
REYNOLDS et al. (1998), "Polymer Erosion and Drug Release Characterization of Hydroxypropyl Methylcellulose Matrices" <i>Journal of Pharmaceutical Sciences</i> <u>87</u> (9):1115-1123.
SHAMEEM et al. (1995), "Oral Solid Controlled Release Dosage Forms: Role of GI-Mechanical Destructive Forces and Colonic Release in Drug Absorption Under Fasted and Fed Conditions in Humans," <i>Pharmaceutical Research</i> <u>12</u> (7):1049-1054.
SIEPMANN et al. (1999) "A New Model Describing the Swelling and Drug Release Kinetics from Hydroxypropyl Methylcellulose Tablets," <i>Journal of Pharmaceutical Sciences</i> <u>88</u> (1):65-72.
YANG et al. (1996), "Zero-Order Release Kinetics from a Self-Correcting Floatable Asymmetric Configuration Drug Delivery System," <i>Journal of Pharmaceutical Sciences</i> <u>85</u> (2):170-173.

As the subject application was filed after June 30, 2003, copies of the U.S. patents and/or publications disclosed in this Information Disclosure Statement are not required and, therefore, are not included.

This Information Disclosure Statement is not intended as a representation that a search has been made, that additional information material to the examination of this application does not exist, or that any of the above references constitutes prior art to the present application within the meaning of 35 USC § 102.

As this Information Disclosure Statement is being filed concurrently with the application,
no fee is required.

Respectfully submitted,

By:


Karen Canaan
Registration No. 42,382

REED & EBERLE LLP
800 Menlo Avenue, Suite 210
Menlo Park, California 94025
(650) 330-0900 Telephone
(650) 330-0980 Facsimile

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
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Sheet

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Complete if Known

Application Number	Divisional of 10/024,932
Filing Date	Filed herewith
First Named Inventor	Bret BERNER et al.
Art Unit	Unassigned
Examiner Name	Unassigned

Attorney Docket Number 3100-0001.10

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.	Document No.	Issue Date or Publication Date	Name of Patentee or Applicant of Cited Document	Class	Subclass	Filing Date if Appropriate
/A.H./	AA	4,434,153	2/28/84	Urquhart et al.			
	AB	4,690,824	9/1/87	Powell et al.			
	AC	4,695,467	9/22/87	Uemura et al.			
	AD	4,748,023	5/31/88	Tamás et al.			
	AE	4,786,503	11/22/88	Edgren et al.			
	AF	4,839,177	6/13/89	Colombo et al.			
	AG	4,851,232	7/25/89	Urquhart et al.			
	AH	4,865,849	9/12/89	Conte et al.			
	AI	4,910,021	3/20/90	Davis et al.			
	AJ	5,002,772	3/26/91	Curatolo et al.			
	AK	5,007,790	4/16/91	Shell			
	AL	5,064,656	11/12/91	Gergely et al.			
	AM	5,085,865	2/4/92	Nayak			
	AN	5,213,808	5/25/93	Bar-Shalom et al.			
	AO	5,232,704	8/3/93	Franz et al.			
	AP	5,393,765	2/28/95	infeld et al.			
	AQ	5,422,123	6/6/95	Conte et al.			
	AR	5,425,950	6/20/95	Dandiker et al.			
	AS	5,458,887	10/17/95	Chen et al.			
	AT	5,458,888	10/17/95	Chen			
	AU	5,464,633	11/7/95	Conte et al.			
	AV	5,472,708	12/5/95	Chen			
	AW	5,487,901	1/30/96	Conte et al.			
	AX	5,508,040	4/16/96	Chen			
	AY	5,549,913	8/27/96	Colombo et al.			
	AZ	5,582,837	10/10/96	Shell			
	BA	5,609,590	3/11/97	Herbig et al.			
	BB	5,626,874	5/6/97	Conte et al.			
	BC	5,650,169	7/22/97	Conte et al.			
	BD	5,651,985	7/29/97	Penners et al.			
	BE	5,681,583	10/28/97	Conte et al.			
	BF	5,688,776	11/18/97	Bauer et al.			
	BG	5,736,159	4/7/98	Chen et al.			
	BH	5,738,874	4/14/98	Conte et al.			
	BI	5,780,057	7/14/98	Conte et al.			
	BJ	5,783,212	7/21/98	Fassihi et al.			
	BK	5,811,126	9/22/98	Krishnamurthy			
	BL	5,837,379	11/17/98	Chen et al.			
	BM	5,840,329	11/24/98	Bai			
	BN	5,840,332	11/24/98	Lerner et al.			
	BO	5,861,173	1/19/99	Nishioka et al.			
/A.H./	BP	5,891,474	4/6/99	Busetti et al.			
	BQ	5,897,874	4/27/99	Stevens et al.			

Examiner Signature	/Andriae Holt/	Date Considered	04/09/2008
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet	2	of	3	Attorney Docket Number	3100-0001.10
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U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.	Document No.	Issue Date or Publication Date	Name of Patentee or Applicant of Cited Document	Class	Subclass	Filing Date if Appropriate
/A.H./	BR	5,916,595	6/29/99	Chen et al.			
	BS	5,945,125	8/31/99	Kim			
	BT	5,972,389	10/26/99	Shell et al.			
	BU	6,033,685	3/7/00	Qiu et al.			
	BV	6,207,197	3/27/01	Illum et al.			
	BW	6,261,601	7/17/01	Talwar et al.			
	BX	6,340,475	01/22/02	Shell et al.			
	BY	6,368,628	4/9/02	Seth			
	BZ	6,451,808	9/17/02	Cowles			
	CA	6,488,962	12/3/02	Berner et al.			
	CB	2001/0018070	8/30/01	Shell et al.			
	CC	Serial No. 09/425,491		Shell et al			10/22/99
	CD	Serial No. 10/029,134		Gusler et al.			10/25/01
	CE	Serial No. 10/045,823		Shell et al.			11/6/01
	CF	Serial No. 10/066,146		Lim et al.			2/1/02
/A.H./	CG	Serial No. 10/152,914		Fara et al.			5/20/02

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.	Foreign Patent Document No.	Publication Date	Country	Class	Subclass	T
/A.H./	CH	GB 1330829	9/19/73	United Kingdom			
	CI	EP 0598309 B1	1/28/98	Europe			
	CJ	EP 0795324 A2	9/17/97	Europe			
	CK	WO 96/32097 A1	10/17/96	PCT			
	CL	WO 98/55107 A1	12/10/98	PCT			
	CM	WO 00/23045 A1	4/27/00	PCT			
	CN	WO 00/38650 A1	7/6/00	PCT			
	CO	WO 01/32217 A3	5/10/01	PCT			
	CP	WO 01/56544 A3	8/9/01	PCT			
	CQ	WO 01/97783 A1	12/27/01	PCT			
/A.H./	CR	WO 02/083687 A1	10/24/02	PCT			

OTHER DOCUMENTS — NONPATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), Title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T
/A.H./	CS	ABRAHAMSSON et al. (1993), "Absorption, Gastrointestinal Transit, and Tablet Erosion of Felodipine Extended-Release (ER) Tablets," <i>Pharmaceutical Research</i> 10(5):709-714.	
	CT	APICELLA et al. (1993), "Poly(ethylene oxide) (PEO) and Different Molecular Weight PEO Blends Monolithic Devices for Drug Release," <i>Biomaterials</i> 14(2):83-90.	
	CU	COLUMBO et al. (1990), "Drug Release Modulation by Physical Restrictions of Matrix Swelling," <i>International Journal of Pharmaceutics</i> 63:43-48.	
/A.H./	CV	CONTE et al. (1996), "Modulation of the Dissolution Profiles from Geomatrix® Multi-Layer Matrix Tabletes Containing Drugs of Different Solubility," <i>Biomaterials</i> 17(9):889-896.	

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(use as many sheets as necessary)

Sheet	3	of	3	Attorney Docket Number	3100-0001.10
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Complete if Known

Application Number	Divisional of 10/024,932
Filing Date	Filed herewith
First Named Inventor	Bret BERNER et al.
Art Unit	Unassigned
Examiner Name	Unassigned

OTHER DOCUMENTS — NONPATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), Title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T
/A.H./	CW	DAVIS et al. (1986), "The Effect of Density on the Gastric Emptying of Single- and Multiple-Unit Dosage Forms," <i>Pharmaceutical Research</i> 3(4):208-213.	
	CX	DESHPANDE et al. (1997), "Development of a Novel Controlled-Release System for Gastric Retention," <i>Pharmaceutical Research</i> 14(6):815-819.	
	CY	GUSLER et al. (June 2001), "Pharmacokinetics of Metformin Gastric-Retentive Tablets in Healthy Volunteers," <i>The Journal of Clinical Pharmacology</i> 41(6):655-661.	
	CZ	HUBER et al. (1966), "Utilization of Hydrophilic Gums for the Control of Drug Release from Tablet Formulations. I. Disintegration and Dissolution Behavior," <i>Journal of Pharmaceutical Sciences</i> 55(9):974-976.	
	DA	HWANG et al. (1998), "Gastric Retentive Drug-Delivery Systems," <i>Critical Reviews in Therapeutic Drug Carrier Systems</i> 15(3):243-284.	
	DB	KATORI et al. (1995), "Estimation of Agitation Intensity in the GI Tract in Humans and Dogs Based on <i>in Vitro/in Vivo</i> Correlation," <i>Pharmaceutical Research</i> 12(2):237-243.	
	DC	KIM (1995), "Drug Release from Compressed Hydrophilic POLYOX-WSR Tablets," <i>Journal of Pharmaceutical Sciences</i> 84(3):303-306.	
	DD	KORSMEYER et al. (1983), "Mechanisms of Solute Release from Porous Hydrophilic Polymers," <i>International Journal of Pharmaceutics</i> 15:25-35.	
	DE	LAPIDUS et al. (1966), "Some Factors Affecting the Release of a Water-Soluble Drug from a Compressed Hydrophilic Matrix," <i>Journal of Pharmaceutical Sciences</i> 55(8):840-843.	
	DF	MAGGI et al. (2000), "Highly Swellable, Multi-Layer Tablets to Prolong the Residence Time of the Delivery Device in the Stomach," <i>Abstracts / Journal of Controlled Release</i> 64:333-334.	
	DG	MAGGI et al. (2000), "High Molecular Weight Polyethylene Oxides (PEOs) as an Alternative to HPMC in Controlled Release Dosage Forms," <i>International Journal of Pharmaceutics</i> 195:229-238.	
	DH	RAO et al. (1988), "Swelling Controlled-Release Systems: Recent Developments and Applications," <i>International Journal of Pharmaceutics</i> 48:1-13.	
	DI	REYNOLDS et al. (1998), "Polymer Erosion and Drug Release Characterization of Hydroxypropyl Methylcellulose Matrices" <i>Journal of Pharmaceutical Sciences</i> 87(9):1115-1123.	
	DJ	SHAMEEM et al. (1995), "Oral Solid Controlled Release Dosage Forms: Role of GI-Mechanical Destructive Forces and Colonic Release in Drug Absorption Under Fasted and Fed Conditions in Humans," <i>Pharmaceutical Research</i> 12(7):1049-1054.	
	DK	SIEPMANN et al. (1999) "A New Model Describing the Swelling and Drug Release Kinetics from Hydroxypropyl Methylcellulose Tablets," <i>Journal of Pharmaceutical Sciences</i> 88(1):65-72.	
/A.H./	DL	YANG et al. (1996), "Zero-Order Release Kinetics from a Self-Correcting Floatable Asymmetric Configuration Drug Delivery System," <i>Journal of Pharmaceutical Sciences</i> 85(2):170-173.	

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